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November 18, 2004

NOV 26

Office of Nutritional Products Labeling
and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

Re: Notification for Statements on Dietary Supplement Labels

Dear Sir/Madam:

This firm represents Renaissance Herbs, Chatsworth, California, a manufacturer and distributor of dietary supplement products. Renaissance Herbs has requested that we notify your Agency on its behalf of the inclusion of a statement of nutritional support on a dietary supplement product label.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the authorized provisions of 21 CFR §101.93(a), your Agency is hereby notified that Renaissance Herbs has made a statement of "nutritional support", as described in 21 U.S.C. §343(r)(6)(A), for a dietary supplement as follows:

Name

Label Statement

Boswellia

Joint and respiratory function.


Two copies of this notification are enclosed with this original document.

97S 0162

LET 15046

The undersigned hereby certifies on behalf of Renaissance Herbs that the information contained in this correspondence is complete and accurate.

Sincerely yours,
GRONEK & ARMSTRONG

A handwritten signature in black ink, appearing to read "Paul J. Wisniewski". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Paul J. Wisniewski

PJW:
pr

Enclosures

CC: Renaissance Herbs